UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

UNITED STATES OF AMERICA, THE DISTRICT OF COLUMBIA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MARYLAND, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW HAMPSHIRE, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WISCONSIN, THE CITY OF CHICAGO AND NEW YORK CITY, THE CALIFORNIA DEPARTMENT OF INSURANCE AND THE ILLINOIS DEPARTMENT OF INSURANCE EX REL. STEPHEN HAMILTON, STEFAN P. KRUSZEWSKI, AND JOHN DOE, [UNDER SEAL],

Relators,

v.

SANOFI S.A.
[UNDER SEAL]
Defendant.

CASE NO.:

FILED UNDER SEAL

PURSUANT TO 31 U.S.C. § 3729 ET. SEQ.

DO NOT PLACE IN PUBLIC RECORD

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT, THE FALSE CLAIMS ACTS OF VARIOUS STATES AND CITIES AND THE INSURANCE FRAUD STATUTES OF CALIFORNIA AND ILLINOIS

This is an action against Defendant Sanofi S.A. for engaging in illegal kickbacks, misbranding, off-label promotion, falsification of records, misleading statements, and best price violations in the sale of its insomnia drugs Ambien and Ambien CR. This case is brought by three Relators: (1) Relator Stephen Hamilton, a former top Sanofi S.A. sales representative; (2) Relator Stefan P. Kruszewski, a psychiatrist who has been detailed by Sanofi S.A. sales representatives; and (3) Relator John Doe, a former marketing executive at Sanofi S.A.'s U.S. Headquarters in Bridgewater, N.J. Relators Hamilton, Kruszewski, and Doe bring this case by and through their undersigned attorneys, on behalf of themselves, the United States of America, the District of Columbia, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, the City of Chicago and New York City ("Plaintiff States and Cities"), as well as the California Department of Insurance and the Illinois Department of Insurance. Relators Hamilton, Kruszewski and Doe aver as follows for their Complaint against Defendant Sanofi S.A. based upon personal knowledge and relevant documents:

I. INTRODUCTION

1. In the very first year it took over the marketing of Ambien, Defendant Sanofi S.A.

("Sanofi" or "Sanofi S.A.") rocketed Ambien from annual sales in the hundreds of millions of dollars into the blockbuster drug range of annual sales of over 1.2 billion dollars and a market Share of over 80%. Through its illegal promotion of Ambien and later, Ambien CR, Defendant Sanofi reaped hundreds of millions of dollars in fraudulent profits. How Sanofi accomplished this marketing success through illegal means is revealed by the unique knowledge and documents possessed by the three relators in this case whose cumulative knowledge of Sanofi's misdeeds spans some 17 years.

2. Relators Stephen Hamilton, Stefan Kruszewski, and John Doe are respectively a former sales representative for Sanofi, a psychiatrist detailed by Sanofi, and a former corporate executive at Sanofi. Through their personal and relevant observations, the evidence in this case shows that Sanofi S.A. utilized kickbacks, off-label marketing, misbranding, clinically unsupported superiority claims, best price violations and falsification of paperwork to increase sales for Ambien and Ambien CR by:

a. Spending millions of dollars on national and international kickbacks ranging from meals for doctors, staff, and nurses to international airfare and accommodations for doctors in order to promote the prescription of Ambien and, later to accomplish their goal of a 50% conversion rate for switching patients from Ambien to Ambien CR without regard to whether switching from Ambien to Ambien CR was in the patients' best medical interest;

b. Maintaining "Return on Investment" reports for meticulous tracking of the results of kickbacks given to prescribing doctors and their staffs so that the kickback money was spent only on those doctors who gave satisfactory quid pro quo in return for receiving the kickbacks; Sanofi rewarded sales representatives who spent their kickback money on the "right" doctors, by giving them more money to spend on even more doctors for more prescriptions;

c. Off-label promoting Ambien and Ambien CR for an enormous range of non-insomnia conditions, including but not limited to: psychiatric disorders such as schizophrenia, depression, anxiety disorders, bipolar disorder, panic disorder, dementia; pediatric disorders; Parkinson's Disease; restless leg syndrome; jet lag; Post-Traumatic Stress Disorder; pre-operation sedation; recovery from surgery; post-menopausal women; rheumatoid arthritis; and medication side effects;

d. Off-label promoting Ambien in higher than approved dosages so as to make greater profits;

e. Off-label promoting Ambien and Ambien CR for use as a prophylaxis against depression and other non-indicated conditions to be co-prescribed to psychiatric patients using SSRI drugs despite the contraindications for use of Ambien and Ambien CR with depressed patients;

f. Misbranding Ambien and Ambien CR for efficacy in the prevention of certain psychiatric disorders, including but not limited to schizophrenia and dementia;

g. Misbranding the true chemical nature of Ambien and Ambien CR so as to make it more appealing to physicians and consumers by marketing the drugs as non-benzodiazepines despite the fact that the essential ingredient – zolpidem – functions identically to benzodiazepine drugs;

h. Asserting false superiority claims about Ambien CR's superiority to Ambien lacking any clinical basis;

i. Falsifying paperwork authorizing the switching of patients from Ambien to Ambien CR and inducing nurses and pharmacists to bypass physicians in switching patients from off-patent Ambien to on-patent Ambien CR;

j. Sanofi leveraged the strength of Ambien in the market place and illegally bundled Ambien CR managed care contracts tied to Ambien in order to gain coverage including in Medicare Part D. In some cases, managed care companies were threatened that they would lose their sizable Ambien rebates if they did not add Ambien CR to their formulary. Sanofi also inflated their profits by constantly taking significant and multiple price increases on Ambien and Ambien CR;

k. Sanofi deceived physicians and managed care companies by lying that there were no clinical studies comparing efficacy of Ambien (which was generic at the time) and Ambien CR. On the contrary, Sanofi had conducted two studies that showed that there were no differences between Ambien and Ambien CR which they refused to publish in medical journals.

3. Sanofi S.A.'s illegal marketing of Ambien allowed it to achieve a market share of 85% only one year after taking over the sales of Ambien and an 88% market share one year later. On information and belief, Sanofi S.A. has reaped enormous illicit profits in the billions of dollars and continues to do so through its illegal marketing of both Ambien and Ambien CR.

II. PARTIES

4. Relator Stephen Hamilton is a citizen of the United States and a resident of the State of California. He was employed by Sanofi S.A. as a sales representative in Los Angeles, California, for more than four years, from 2001 - 2007, and a sales representative for Bristol-Meyers Squibb from 1997 - 2001.

5. Relator Stefan P. Kruszewski is a citizen of the United States and a resident of the State of Pennsylvania where he practices medicine. During the scope of his practice, Sanofi sales representatives detailed Dr. Kruszewski on Ambien and also asked him to speak about Ambien.

6. Relator John Doe is a citizen of the United States and a resident of the State of New Jersey. He was employed by Sanofi S.A. as a corporate executive for more than ten years, from 2000 - 2010.

7. Defendant Sanofi S.A. is a global pharmaceuticals company with its United States headquarters located in Bridgewater, New Jersey. It is incorporated in the State of Delaware. Sanofi S.A. has its headquarters in Paris, France with subsidiary companies in over 21 countries, including the United States.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. §3730(e) as amended, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relators, moreover, qualify under that section of the False Claims Act as an "original source" of the allegations in this Complaint even had such a

public disclosure occurred.

9. Upon the filing of this complaint, Relators shall concurrently serve upon the Attorney General of the United States, the United States Attorney for the District of Massachusetts, the offices (or other State offices designated by statute) of Plaintiff States' Attorney Generals, the city clerk for the City of Chicago, the New York City Department of Investigation, the California Insurance Commissioner, and the Illinois Department of Insurance, the complaint and a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. § 3730(b)(2). The disclosure statement is supported by material evidence. Because the disclosure statement includes attorney-client communications and work product of Relators' attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential and the initial disclosure statement and all documents provided therewith, and all supplements thereto, are incorporated herein by reference.

10. This Court has personal jurisdiction and venue over the Defendant pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because those sections authorize nationwide service of process and because Defendant has minimum contacts with the United States. Moreover, Defendant can be found in, resides in, and transacts business in this District. This Court has supplemental jurisdiction over the State law claims pursuant to 28 U.S.C. § 1367(a).

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed by Defendant in this District. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) & (c) and 31 U.S.C. § 3732(a).

IV. BACKGROUND

12. In 1992, the FDA approved Ambien (zolpidem tartrate), a schedule IV drug, for use in the treatment of short-term insomnia. Defendant Sanofi did not fully take control of the sales and marketing of Ambien until on or about the year of 2002. In the year prior to Sanofi taking over the sales and marketing of Ambien, the 2001 sales of Ambien in the United States were $900 million. In 2002, the very first year that Sanofi took control of Ambien's marketing and sales, the annual sales report showed United States sales of Ambien jumping to blockbuster-drug status with U.S. sales of over 1.2 billion dollars. From 2003 through 2007, Sanofi's marketing budget for Ambien and Ambien CR averaged 185 million dollars per year. This enormous investment allowed Ambien to gain a market share of as high as 88% and maintain a combined market share with Ambien CR in the 45% range even in the face of generic competition and other insomnia competitors like Lunesta.

13. Defendant Sanofi was only able to accomplish this enormous jump in sales and maintain its profits through illegal kickbacks, off-label marketing, misbranding, best price violations and numerous other improper and illegal practices. The relators in this case have unique and extensive personal knowledge of Sanofi's illegal marketing of Ambien and Ambien CR as well as other drugs sold by Sanofi such as Plavix, Avapro, and Uroxatral. Collectively, their years of insider knowledge of Sanofi's misdeeds span a total of some 17 years.

14. Relator Stephen Hamilton was a sales representative employed by Sanofi. His employment responsibilities included marketing and selling Ambien as well as Ambien CR to physicians and their staffs. He is an original source of the facts and information set forth in this complaint. Relator Hamilton is uniquely qualified to serve as a relator in this case having worked in pharmaceutical sales for over a decade. Prior to his Ambien and Ambien CR sales

responsibilities, he worked for Bristol-Myers-Squibb from 1997 through 2001 selling Pravachol, Glucophage, Monopril, and Plavix. His duties at both companies included the planning and coordination of sales budgets for his territories, business plans, and sales programs directed at physicians and nurses. Relator Hamilton holds a Bachelor of Science in Business Administration from California State University at Sacramento. His territory for the sales of Ambien and Ambien CR included Beverly Hills, California.

15. Relator Stefan P. Kruszewski is a psychiatrist who was subjected to improper marketing by Defendant Sanofi. Dr. Kruszewski was detailed by Sanofi sales representatives on Ambien and asked to speak about Ambien. He is an original source of the facts and information set forth in this complaint. Relator Kruszewski is uniquely qualified to serve as a relator in this case having worked as a health-care fraud auditor, investigator and consultant for several organizations, including Capital BlueCross of Harrisburg, Pennsylvania, AllMed of Portland, Oregon, and the Department of Public Welfare for the Commonwealth of Pennsylvania. Relator Kruszewski's critical review of the claims about Ambien and Ambien CR made by Sanofi have allowed him to expose Sanofi's misleading marketing efforts as being medically and scientifically unsound. Relator Kruszewski holds an A.B. in Biochemistry from Princeton University and a medical degree from Harvard Medical School.

16. Relator John Doe is an executive with over 15 years of experience in the pharmaceutical industry. He was employed by Sanofi S.A. from 2000 through 2010 where his employment duties included serving as a Marketing Director with a portfolio including Ambien, Ambien CR and other drugs. He is an original source of the facts and information set forth in this complaint. Relator Doe is uniquely qualified to serve as a relator in this case due to his leadership roles in the marketing of Ambien, Ambien CR, and the launch of Ambien CR as well

in the marketing of Uroxatral and other Sanofi drugs. Relator Doe holds degrees in Microbiology, Pharmacy and Business.

17. Beginning at least in 2001, if not earlier, Defendant Sanofi misbranded and off-label marketed Ambien and supported such illegal sales techniques through an extensive system of kickbacks totaling in the millions of dollars. Although Ambien had only been approved for use in treating insomnia and its label stated that it was effective for sleep onset, Defendant misbranded Ambien by claiming it was also effective at sleep maintenance. Defendant promoted Ambien in off-label dosages higher than authorized by the label. Defendant promoted Ambien for off-label long-term use prior to ever receiving authorization for such long-term use. Defendant promoted Ambien for a variety of off-label uses through its sales force as well as through the illegal practice of having its Continuing Medical Education department work directly with its marketing department to insert off-label messages and information in its "educational" materials. This practice made the Continuing Medical Education department merely an arm of the Marketing Department.

18. Beginning at least in 2005, if not earlier, the imminent expiration of Ambien's patent threatened Sanofi's profits with the lower prices generics would soon offer. To counter this potential loss of revenue, Sanofi hoped to convince doctors prescribing Ambien to their patients to switch their patients to the more profitable Ambien CR. But Sanofi's switching plan faced numerous obstacles, including the belief of many managed care companies and physicians that Ambien CR had only been created because the Ambien patent was expiring and also because Ambien CR was not yet on all insurance company formularies. To counter these obstacles, Sanofi devoted hundreds of millions of dollars to illegal marketing efforts to switch Ambien patients to Ambien CR without regard to whether such switching was in the best interests of the

patient or medically necessary.

19. The illegal plan included the misbranding of Ambien CR as well as Ambien by claiming non-existent differences between the two drugs. For example, Ambien CR was promoted as having improved sleep latency even though Sanofi knew that clinical trials had failed to validate such claims. Similarly, although Sanofi had once promoted Ambien as being effective at sleep onset and sleep maintenance, once Ambien CR was launched, it began claiming that Ambien CR was superior to Ambien because Ambien was only good for sleep onset. A massive system of kickbacks was utilized to switch Ambien users to Ambien CR. These kickbacks ranged from paying for the meals of doctors, nurses and pharmacists to flying doctors on international all-expense paid trips for "conferences" and as part of training to be a "speaker" for Sanofi. Sales representatives were instructed to teach nurses and other medical staff how to falsify authorization forms in order to switch patients to Ambien CR without regard to whether the patient needed to be switched. Sanofi profited greatly from these illegal actions as both Ambien and Ambien CR have generated hundreds of millions of dollars a year in profit for Sanofi.

20. In 2010, Sanofi S.A. realized revenue of just over $30 billion Euro. With its acquisition of Genzyme Corporation in Boston, Massachusetts in 2011, Sanofi is expected to overtake Pfizer as the number one pharmaceutical company in the world in sales.

V. APPLICABLE LAW

A. Federal & State False Claims Acts

21. Relators seek to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States and Cities arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant and/or

its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq., as amended (the FCA) or (the Act) and its state-law counterparts: the District of Columbia False Claims Act, D.C. Code Ann. § 2-381.02 et seq.; the California False Claims Act, Cal. Gov Code § 12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stats. § 25.5-4-305 et seq.; the Connecticut False Claims Act, Conn. Gen. Stats. § 17b-301(a) et seq.; the Delaware False Claims and False Reporting Act, Del. Code Ann. Ti 6,§ 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 et seq.; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Maryland False Health Claims Act of 2010, Md. Code Ann., § 2-601 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12§ 5 et seq.; the Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.601 et seq.; the Minnesota False Claims Act, Minn. Stat. § 15C.01 et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 et seq.; the New Hampshire False Claims Act, § 167:61-b et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§ 27-14-1 et seq.; the New Mexico Fraud Against Taxpayers Act, N.M. Stat. § 44-9-1 et seq.; the New York False Claims Act, State Finance Law § 187 et seq.; the North Carolina False Claims Act, N.C. Gen. Stat § 1-605 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat Ann. Tit 63. § 5053, et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.; the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 et seq.; the Texas Medicaid Fraud

Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931, et seq.; the Chicago False Claims Act, Chicago Municipal Code, ch. 1-22 et seq., the New York City False Claims Act, N.Y.C. Admin. Code § 7-801, et seq., the California Insurance Fraud Protection Act, Cal. Ins. Code § 1871.7, and the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92/1.

22. Pursuant to these laws, Relators bring this action on behalf of the United States and the Plaintiff States and Cities to recover the hundreds of millions of dollars Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service have been fraudulently induced to pay as a result of false and/or fraudulent Ambien and Ambien CR reimbursement claims submitted by, and caused to be submitted by Defendant.

23. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

24. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery.

B. The FDA Regulatory Scheme

25. Under the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. §§ 301-97, new

pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration (FDA) that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355 (a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

26. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

27. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

28. Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. § 360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the

drug is approved to treat adults).

29. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

30. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

31. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. § 360aaa(b)&(c).

32. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of its products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses. With regard to the first practice, disseminating written information, the FDAMA only permits a manufacturer to disseminate information regarding off-

label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

33. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

34. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and

effective by an independent, scientific governmental body, the FDA.

35. Defendant, unable to bolster revenues for Ambien and Ambien CR through legitimate drug reimbursement claims to Medicaid and Medicare and the other government-funded healthcare programs named herein, instead launched a campaign intended to increase Government-funded off-label purchases of these drugs by marketing Ambien and Ambien CR for non-medically accepted indications to physicians and psychiatrists. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused such physicians and/or pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

36. Each such claim Defendant knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to cause claims for Ambien and Ambien CR to be paid, constitutes a false claim for which Defendant is accountable under the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities.

C. Regulations Restricting Reimbursement for Off-label Prescription Drug Uses by Government-Funded HealthCare Programs

37. Payment for off-label uses of prescription drugs by government-funded healthcare programs is highly regulated and restricted pursuant to the laws set forth below.

38. When drug manufacturers promote their drugs off-label, this causes the submission of false claims to, inter alia, government-funded health care programs.

D. The Medicaid Act

39. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and

State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries. On January 1, 2006, Medicare Part D went into effect.

40. A State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services to participate in the Medicaid program. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. Id. at §§ 1396b(a)(I), 1396d(b).

41. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

42. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under

section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(I). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

43. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97, 98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(l)(B)(ii). Relevant hereto is the provision which permits a State to exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(l)(B)(i).

44. Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. §§ 355 & 357. It does not include "a drug or biological use for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

45. The statute defines "medically accepted indication" as: "any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." Id. at § 1396r-8(k)(6).

46. The three compendia identified in subsection (g)(I)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System. Id. at § 1396r-8(g)(l)(B)(i).

47. Upon information and belief, the most commonly available of these compendia, DRUGDEX, does not support the off-label uses for Ambien and Ambien CR promoted by Sanofi

S.A.

48. Similarly, off-label indications qualify as "medically accepted indications" for Medicare reimbursement if they appear on the identified drug reporting compendia.

49. DRUGDEX is a proprietary information service provided by a division of the Thomson Reuters Corporation. DRUGDEX is unique in that it is designated by the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 352(f)(1), the FDA Modernization Act of 1997 and FDA implementing regulations as a statutory compendium, and is the only such compendium that continues to publish detailed clinical information pertaining to pharmaceutical products.

50. Discussions of "therapeutic uses" for all drugs approved by the FDA are found within Section 4.5 of the DRUGDEX entry for that drug. These reviews include both FDA-approved and off-label indications. Material cited with respect to off-label indications can be used by the Centers for Medicaid and Medicare (CMS) in making decisions about the eligibility of claims made for reimbursement of the cost of program beneficiaries' prescription drugs. The specific content of DRUGDEX recommendations is therefore critical.

51. DRUGDEX assigns to each evaluated therapeutic use a "Class" which identifies whether a drug is recommended and/or efficacious for that use. Uses that DRUGDEX lists as Class III are not considered medically accepted indications for the purposes of determining coverage policy.

52. Defendant knew or should have known of the Medicaid regulations governing prescription drug reimbursement.

53. At all times relevant to this Complaint, the United States and the Plaintiff States and Cities were unaware of the unlawful manner in which Defendant promoted Ambien and

Ambien CR throughout the United States.

54. Hereinafter off-label and non-medically accepted indication shall be used interchangeably.

E. The Anti-Kickback Statute

55. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs. In other words, claims arising from an unlawful exchange violative of the Anti-Kickback Statute are, as a matter of law, ineligible for reimbursement and upon submission are false claims subject to the provisions of the Federal False Claims Act, 31 U.S.C. § 3729 et seq.

56. Guidance from the Department of Health and Human Services Office of Inspector General (HHS/OIG) notes that payments to physicians who had offered no particular services of benefit to a pharmaceutical company, but who had generated in the past, or had the potential to generate in the future, a great deal of business for the drug company would be a suspect practice. See Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65, 376 (Dec. 19, 1994). Indeed, many of the practices utilized by Sanofi in this case are specifically cautioned against:

a. Improper Consulting and Advisory Payments: Payments to physicians for simply attending meetings or conferences in a passive capacity, or for services connected with a manufacturer's marketing activities;

b. Improper Payments for Detailing: Payments to physicians for time spent listening to sales representatives market pharmaceutical products;

c. Improper Business Courtesies and Other Gratuities: Gifts of more than a trivial value, entertainment, recreation, travel, meals and other gratuities furnished in association with information or marketing presentations.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg 23731 (May 5, 2003).

57. The guidance from HHS/OIG further cautions that "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." Id.

58. By engaging in the fraudulent and illegal practices described herein, Defendant Sanofi violated the Anti-Kickback Statute and, in turn caused false claims to be submitted in violation of the Federal False Claims Act, § 3729(a)(1)A). Specifically, Defendant's material violations of the Anti-Kickback Statute led to the submission of claims for Defendant's drug to the United States for payment. Those claims were false, as they were ineligible for reimbursement, and by submitting or causing these false claims to be submitted, Defendant further violated Section 3729(a)(1)(A) from at least as early as 2004 and continues to do so through the present day.

VI. ALLEGATIONS

A. Defendant Sanofi S.A. Paid Millions of Dollars in Kickbacks in Return for Doctors Writing Prescriptions for Ambien and Ambien CR and for Switching Patients from Ambien to Ambien CR for No Medical Reason

59. As stated previously, Ambien and Ambien CR's enormous revenues were accomplished through illegal marketing practices including millions of dollars in illegal kickbacks to physicians, nurses, pharmacists and other medical staff in order to "buy" their prescribing of Ambien and Ambien CR.

60. By paying millions of dollars in kickbacks, Defendant Sanofi sought to "buy" the prescribing done by doctors, nurses, medical staffs and pharmacists. At the corporate level, Sanofi S.A. executives spoke openly of seeking to "own" doctors and researchers in the sleep research field and set a goal of at least 50% conversion rate of existing Ambien patients to Ambien CR.

61. In some instances, Sanofi deliberately turned a blind eye to doctors and pharmacies whose prescription volume and practices strongly suggested the doctors and pharmacies were engaged in Medicaid and Medicare fraud even after such evidence was brought to their attention by sales representatives.

B. Types of Kickbacks Utilized by Sanofi S.A.

62. "International Conferences" were held from 2003 through 2009 for which Sanofi S.A. spent millions of dollars paying for airfare, accommodations at hotels and resorts, meals and alcohol, ground transportation and honoraria with the explicit purpose of seeking to "own" doctors and researchers and to promote misbranding and off-label marketing of Ambien and Ambien CR. "Access Funds" in the millions of dollars were budgeted for providing gifts, gratuities, and meals to doctors, nurses, pharmacists and medical staff. "Lunch/Learn" was the term Defendant used for the millions of dollars spent providing meals to doctors and their staffs so that the doctors and their staff would prescribe Ambien and Ambien CR as well as switch existing Ambien patients to Ambien CR at the request of Sanofi sales representatives. In 2005, for example, Sanofi spent $6.4 million dollars on its Lunch/Learn programs for Ambien and Ambien CR. In 2006, it spent $9.2 million dollars on Lunch/Learn programs and budgeted $16.7 million including $7 million for "Access Funds" and $9.7 million for "Speaker Programs" for Ambien CR only.

63. "Speaker Programs" was the term Defendant used for paying millions of dollars to doctors who were designated speakers, trained in off-label uses of both drugs and then sent to meet with other doctors to market Ambien and Ambien CR and to advocate off-label uses of both drugs as well as the medically unjustified switching of patients from Ambien to Ambien CR, all so that Sanofi could avoid losing money with the introduction of generic alternatives to Ambien. "Speakers" were paid as much as $100,000 a year and the positions were often explicitly bargained for by doctors who threatened to prescribe other drugs unless they were made "Speakers." In 2006, for example, Sanofi spent $9.7 million dollars on its speaker programs.

C. Beginning as Early as 2001 Sanofi Gave Sales Representatives Like Relator Hamilton Thousands of Dollars Each Month of Access Funds To Spend On Gifts, Gratuities and Meals to Doctors, Nurses, Pharmacists and Other Medical Staff Through Such Programs as "Lunch and Learn" In Order to Buy Their Prescribing of Ambien and Ambien CR and to Switch Patients from Ambien to Ambien CR

64. From 2001 to 2005 Sanofi doled out millions of dollars in illegal kickbacks for the prescribing of Ambien through its sales representatives.

65. Sanofi specifically instructed its sales representatives like Relator Hamilton to target physicians identified as being high-volume state Medicaid physicians and Hamilton frequently participated in "blitz campaigns" directed at such targets. In a 2004 mid-year review, Hamilton's supervisor Rodney Carr put in writing the instruction that Hamilton should "focus on high-volume Medi-Cal physicians."

66. Kickbacks were a crucial part of buying the prescribing of Ambien from targeted doctors and their offices. Doctors were invited to lunches and dinners at expensive restaurants and many of the doctors came to expect such supplementation of their income. Some dinners featured other doctors who were part of Sanofi's "Speaker Program." Sales representatives

would help prepare the speaking doctor's presentation usually from a set of speaker decks developed from Sanofi US Corporate which frequently included misbranding and off-label information. The representatives were instructed to "track" doctors who attended such events so that the representatives could ensure the doctors wrote Ambien prescriptions.

67. Some notable examples of the lavish meals given to doctors as gifts in an effort to influence them to prescribe Ambien include two dinners that were part of Sanofi's Speaker Program:

a. $1,299.53 for a dinner program held on October 3, 2003 in Beverly Hills, California at the Lawry's restaurant.

b. $1,259.72 for a dinner program held on November 4, 2004 in Beverly Hills, California also at the Lawry's restaurant.

68. Kickbacks also took the form of paying for the meals of medical staff for targeted physicians. One doctor explicitly told Relator Hamilton that he would only prescribe Ambien if catered lunches were brought to his office staff. On information and belief, Relator Hamilton submits that such explicit quid pro quos were widespread.

D. Sanofi Management Ignored Obvious Indicia of Healthcare Fraud Reported By Their Own Sales Representatives

69. Relator Hamilton reported to his supervisors that a number of Medicare doctors in his region wrote extraordinarily high numbers of prescriptions for not only Ambien but also other Sanofi medications such as Plavix, Sonata, Pletal, Cozaar and Hyzaar. In some instances, hundreds of Ambien prescriptions were being written every month by certain physicians – such volume was well in excess of similar practices.

70. For example, typical doctors for Hamilton's territory averaged 20 Ambien prescriptions per month. In contrast, for the month of December 2005, these doctors wrote the following numbers of Ambien prescriptions:

- 438 (Dr. Lilia Wexley);
- 200 (Dr. Marina Berger);
- 150 (Dr. Tsilya Bass);
- 118 (Dr. Valery Shulman);
- 117 (Dr. Marina Kovalesvsky);
- 99 (Dr. Chetver);
- 65 (Dr. Cherkassky);
- 256 (Dr. Pilossyan – who was previously arrested for Medi-Cal fraud)

71. These same physicians also wrote unusually high amounts of prescriptions for Plavix – a cardiology drug used after strokes. For example, typical doctors in Hamilton's territory averaged 5-8 Plavix prescriptions per month. The biggest prescribing cardiologist might prescribe 30 Plavix prescriptions per month. In contrast, for the month of December 2005, the following doctors wrote in numbers exceeding a cardiologist's office:

- 52 (Dr. Wexley);
- 50 (Dr. Berger);
- 32 (Dr. Shulman);
- 30 (Dr. Kovalevsky);
- 65 (Dr. Pilossyan)

72. Relator Hamilton informed his managers that he had learned these physicians might be engaged in a Medicare fraud conspiracy with one or more pharmacies, and that some of the doctors' offices appeared to lack proper examination rooms. Hamilton also reported that he found it odd that these offices seldom seemed very busy with patients despite the very high numbers of prescriptions being written. In response, his managers directed him to ignore the suspicious activity.

73. Hamilton also told his supervisor that one of the pharmacies utilized by these same doctors would be willing to aid in conversion of patients with a $3000 "grant." The supervisor's response to Hamilton was to instruct Hamilton to "make sure the money gets to the right person." Relator Hamilton ultimately refused to go along with this demand for a bribe.

74. In 2007, Relator Hamilton took leave from his job for disability. At that time he